K031719

JUL 2 2003

1.4 510(k) Summary of Safety and Effectiveness

Submitted by:	Nobel Biocare AB
Address:	15 Bohusgatan Göteborg, SE-402 26 Sweden
Name of Contact Person:	Elizabeth J. Mason, Sr. Regulatory Affairs Specialist
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Date of Submission:	May 30, 2003
Classification Name:	Endosseous Dental Implant (21 CFR 872.3640)
Trade or Proprietary or Model Name:	Esthetic Zirconia Abutment
Legally Marketed Device:	Ceramic Abutment (K913255)

Device Description:
Nobel Biocare's Esthetic Zirconia Abutment incorporates a material change to the predicate device, Ceramic Abutment (K913255). The intended use of the modified Esthetic Zirconia Abutment, as described in its labeling, has not changed from the unmodified device, Ceramic Abutment (K913255), as a result of this modification. Like the original device, Ceramic Abutment (K913255), the Esthetic Zirconia Abutment is intended for use as an anchor to which prosthetic devices, such as artificial teeth, may be attached using dental cement to restore a patient's chewing function.

The material change consists of using Zirconium Oxide, rather than Aluminum Oxide, in the manufacturing of the device. In order to improve esthetics, a whiter prosthetic device is desired within the dental industry. To achieve this, Nobel Biocare's Esthetic Zirconia Abutment will be manufactured using Zirconium Oxide powder, rather than Aluminum Oxide powder utilized in the predicate device, Ceramic Abutment (K913255).

The FDA previously cleared the Zirconium Oxide powder *(trade name: Y-TZP Powder)* under 510(k) number K010630.

Indications for Use:
Nobel Biocare's Esthetic Zirconia Abutment is indicated for the treatment of partially edentulous patients requiring prosthetic devices and/or endosseous implants to restore chewing function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2003

Nobel Biocare AB
C/O Ms. Elizabeth J. Mason
Nobel Biocare USA, Incorporated
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K031719
Trade/Device Name: Esthetic Zirconia Abutment
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: NHA
Dated: May 30, 2003
Received: June 3, 2003

Dear Ms. Mason:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.3 Statement of Indications for Use

510(k) number *(if known)*: K031719

Device Name: Esthetic Zirconia Abutment

Indications for Use:
Nobel Biocare's Esthetic Zirconia Abutment is indicated for the treatment of partially edentulous patients requiring prosthetic devices and/or endosseous implants to restore chewing function.

(Please do not write below this line – Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Kean Mulley for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control. Dental Devices

510(k) Number: K031719